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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,811	07/23/2003	Anthony David Auffret	PC25042A	2538
28523	7590	09/21/2004	EXAMINER	
PFIZER INC. PATENT DEPARTMENT, MS8260-1611 EASTERN POINT ROAD GROTON, CT 06340			HENRY, MICHAEL C	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/626,811

**Applicant(s)**

AUFFRET ET AL.

**Examiner**

Michael C. Henry

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-10 is/are rejected.
- 7) ☐ Claim(s) 7 and 11-29 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

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### **DETAILED ACTION**

Claims 1-29 are pending in application

#### ***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

#### ***Information Disclosure Statement***

The information disclosure statement filed complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file and the information referred to therein has been considered as to the merits.

#### ***Claim Objections***

Claims 7 and 11-29 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and/or cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 7 and 11-29 **have not been further** treated on the merits.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Mori et al. (DE 2737947, Abstract Only).

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In claim 1, applicant claims "A process for preparing a dosage form, which affords a low viscosity solution when placed in the mouth of the consumer, which process comprises the steps of

- (a) preparing a hydrated polymer composition comprising pullulan and sodium alginate having a viscosity suitable for casting;
- (b) casting said composition into the shape of a dosage form; and
- (c) drying said dosage form under such conditions as to provide a form which rapidly dissolves and disperses in the mouth of the consumer."

Mori et al. disclose applicant's process for preparing a film comprising pullulan and sodium alginate, which process comprises (a) preparing a solution polymer composition comprising pullulan and sodium alginate having a viscosity suitable for casting; (b) casting said composition into the shape of a film (a dosage form); and (c) drying said film (dosage form) (see abstract). It should be noted that although Mori et al. is silent about the properties or characteristics of the form which pertains to its ability to rapidly dissolve and disperse in the mouth of a consumer, Mori et al.'s composition is the same as applicant's composition (which also comprises pullulan and sodium alginate) and is prepared by the same method, and consequently should inherently possess the same properties.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leung et al. (WO 00/18365).

In claim 1, applicant claims "A process for preparing a dosage form, which affords a low viscosity solution when placed in the mouth of the consumer, which process comprises the steps of

- (a) preparing a hydrated polymer composition comprising pullulan and sodium alginate having a viscosity suitable for casting;
- (b) casting said composition into the shape of a dosage form; and
- (c) drying said dosage form under such conditions as to provide a form which rapidly dissolves and disperses in the mouth of the consumer."

Leung et al. disclose a process for preparing a physiologically consumable film (a dosage form), which process comprises the

- (a) preparing a hydrated polymer composition comprising pullulan suitable for casting;
- (b) casting said composition into the shape of a film (dosage form); and
- (c) drying said dosage form to provide a form which dissolves and in the mouth of a consumer (see examples, page 31, line 11 to page 31, line 12; see also claims 18, 29 and 30). In addition, Leung et al. disclose that their composition can contain mixtures of water soluble film formers such as pullulan and sodium alginate (see claim 29).

The difference between the applicant's claimed method and the method of Leung et al. is that Leung et al. do not specifically exemplify the use of sodium alginate together with pullulan

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in their preparation. However, Leung et al. disclose that their composition can contain mixtures of the water soluble film formers, pullulan and sodium alginate (see claim 29).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, to have used the method of Leung et al., to prepare a composition comprising pullulan and sodium alginate to be used for oral consumption, since Leung et al. disclose that pullulan and sodium alginate can be combined to form a physiologically consumable film.

One having ordinary skill in the art would have been motivated to have the method of Leung et al., to prepare a composition comprising pullulan and sodium alginate to be used for oral consumption, since Leung et al. disclose that pullulan and sodium alginate can be combined to form a physiologically consumable film. Dependent claims 2-6 which are drawn to said method wherein the composition also comprises one or more pharmaceutically active agents and the composition is adjusted to specific pH range with specific acids including citric acid, are also encompassed by this rejection since Leung et al. disclose the use of a pharmaceutically active agent (an antimicrobial) in the composition and disclose the use the citric acid in the composition (see claims 1 and example 19, page 43, line 21). Furthermore, although Leung et al. do not disclose the pH of their composition, the adjustment of the pH is a matter of choice and does not appear to affect the composition formed. Dependent claim 8 which is drawn to the process of claim 1 wherein the composition also contains one or both of the enzymes pullulanase and alginate lyase, is also rejected as been obvious over Mori et al., since it is common and obvious to use or add enzymes that specifically catalyze the breakdown of substrates (such as pullulan and alignate) that are constituents of consumable compositions as to facilitate the digestion of

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said substrates. Dependent claims 9 and 10 which is drawn to the process of claim 1 wherein the composition or dosage form is irradiated with gamma-radiation at specific amounts, are also rejected as been obvious over Mori et al., since gamma irradiation is commonly applied in processing or sterilization of foods, consumables and the like.


***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

MCH

September 17, 2004.

  
SAMUEL BARTS  
PRIMARY EXAMINER  
GROUP 1200